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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,919

02/25/2004

Victor Morrison Young

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EXAMINER

SASAN, ARADHANA

ART UNIT

PAPER NUMBER

1609

MAIL DATE

DELIVERY MODE

04/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,919

Applicant(s)

YOUNG, VICTOR MORRISON

Examiner

Aradhana Sasan

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/25/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claim 8 was cancelled.
2. Claims 1-7, and 9-15 are being presented for examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 02/25/2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alex et al. (WO 00/28942) in view of Yamamoto et al. (US 4,408,641).

The claimed invention is a process and apparatus for filling capsules with a liquid, the process includes a holding period before sealing the capsule, which allows stabilization of the capsule contents and excess gas to be released.

Alex teaches a process for the manufacture of liquid filled capsules, in particular a process to encapsulate shear sensitive fill material. Alex teaches capsule shells made of gelatin or "other suitable physiologically acceptable macromolecular materials in form of gels", and includes hydroxypropyl methylcellulose (HPMC) capsules (Page 1, lines 8-12). The process of filling the hard gelatin capsules is taught (Page 8, lines 5-6 and Page 9, Table 1b). The process of encapsulating a shear sensitive fill mass into a capsule is also disclosed (Page 4, lines 15-17). Since a person having ordinary skill in the art knows that HPMC capsules are substitutes for hard gelatin capsules, the process taught by Alex for the hard gelatin capsules would be obvious for HPMC capsules. This reference teaches that the empty capsules (prior to filling) "are oriented so that all point in the same direction (i.e. body-end downward)" (Page 3, lines 14-15). Since the capsules will be filled, an upright orientation would be obvious in order to ensure that the filling remain in the capsule. After the capsules are filled, "the cap and body bushing portions are rejoined" (Page 3, lines 25-26).

Alex does not expressly teach the stabilization of the liquid fill contents of hard capsules.

Yamamoto teaches an apparatus for filling viscous substances into hard gelatin capsules. As mentioned above, a person having ordinary skill in the art would find HPMC capsules obvious over hard gelatin capsules, both types being hard and incompressible. Yamamoto allows for contents of liquid filled capsules to be "accommodated" so that the liquid does not "ooze out from the fitting portion between the body and cap portion of the capsule with the lapse of time" (Col. 8, lines 7-14). In

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order to prevent the liquid fill from oozing out of the capsule, it would be obvious to one skilled in the art that the "accommodated" contents would be stabilized, and the excess pneumatic pressure would be released. A person skilled in the art would vary the holding time to ensure that the contents were stabilized and the pressure was released. The holding time (5-300 seconds) would have been obvious to one skilled in the art during the process of routine experimentation and optimization. Therefore, the limitations of instant claims 1-2 would have been obvious to one skilled in the art over Alex, in view of Yamamoto.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fill hard capsules with liquid, as suggested by Alex, in view of the contents stabilization as suggested by Yamamoto and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the integrity of the liquid filled capsules (preventing the oozing of liquid as taught by Yamamoto, Col. 8, lines 7-14) would be more advantageous in light of the higher bioavailability of liquid filled dosage forms over solid dosage forms (Alex, Page 2, lines 4-7).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary

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skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 3-5, the limitations of solidifiable liquid fill would have been obvious to one skilled in the art given the liquid filled (and shear sensitive or thixotropic fill) capsules taught by Alex, in view of the "thermally fusible substance" and thixotropic gel taught by Yamamoto (Col. 1, line 65-68 and Col. 2, lines 1-11).

The limitation of 80-95% of the capsule body filled with the liquid fill of instant claim 6 would have been obvious to a person having ordinary skill in the art because during the process of routine experimentation, the percentage of liquid fill in the capsules would be modified to optimize the integrity of the capsules (prevent oozing of the contents, or bursting of capsules), as well as optimize the desired dosage of the active ingredient and stability profile.

The holding period (10-100 seconds) limitation of instant claim 7 would have been obvious to a person having ordinary skill in the art because the holding time would be modified during the process of routine experimentation to ensure that contents were stabilized and pressure was released.

The limitation of a sealing material applied to seal the cap to the body of the capsule of instant claim 9 would have been obvious to a person having ordinary skill in the art given the liquid filled capsules taught by Alex, in view of the Yamamoto teaching

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that a "suitable sealing agent is filled into a remaining space of the capsule body ..."
(Col. 8, lines 12-13).

Claims 10-15 are drawn to an apparatus for filling a HPMC capsule comprising (i) means for introducing the liquid into the capsule, (ii) means for fitting a capsule cap over the capsule body, and (iii) means for holding the closed capsule upright.

Yamamoto teaches "an apparatus which is capable of filling viscous substances into hard gelatin capsules in an efficient manner" (Col. 2, lines 12-15). The means for filling the hard capsules is disclosed (Col. 2, lines 21-50). The means for fitting a capsule cap over a capsule body is disclosed (Col. 7, lines 21-37). The means for holding closed capsules upright would have been obvious to one skilled in the art given the contents stabilization as stated above.

Regarding instant claim 10, the limitations of the means for filling a HPMC capsule, including the means for introducing the liquid, means for fitting a capsule cap over the capsule body, and means for holding the closed capsule upright would have been obvious to a person having ordinary skill in the art given the liquid filled capsules taught by Alex, in view of the means for filling and closing hard capsules, and the "accommodated" capsule contents taught by Yamamoto.

Regarding instant claim 11, the limitation of the closed capsules held in a vertical array would have been obvious to a person having ordinary skill in the art given the liquid filled capsules taught by Alex, in view of the "accommodated" capsule contents

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taught by Yamamoto. If the capsules are not held in an upright position, the contents cannot be stabilized.

The holding period (10-100 seconds) limitation of instant claim 12 would have been obvious to a person having ordinary skill in the art because the holding time would be modified during the process of routine experimentation to ensure that contents were stabilized and pressure was released.

The limitation of closed capsules being ejected into the lower end of an upright tube of instant claim 13 would have been obvious to a person having ordinary skill in the art because in order to maintain the process efficiency, the closed capsules would have to be maintained upright to prevent the liquid fill contents from being unstable and consequently oozing out or causing the capsules to burst. An upright tube would be an obvious choice to accomplish the stabilization of the closed capsules.

The limitation of non-return means to prevent the bottom-most capsules from falling back of instant claim 14 would have been obvious to a person having ordinary skill in the art because if capsules were allowed to fall back, the process of ejecting capsules into the tubes would be stalled and the whole capsule filling process would become inefficient.

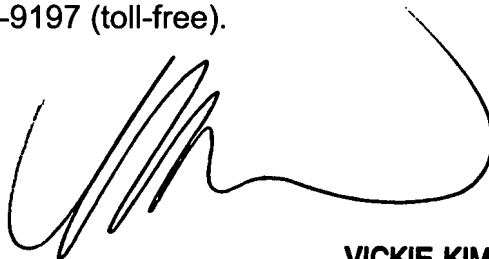
The limitation of capsules ejected from the top of the upright tubes of instant claim 15 would have been obvious to a person having ordinary skill in the art because after the contents of the liquid filled capsules had stabilized, the capsules would be ejected. Alex teaches the use of compressed air to eject capsules (Page 3, line 28).

Conclusion

1. No claims are allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'VICKIE KIM', with a large, sweeping loop at the end.

**VICKIE KIM
PRIMARY EXAMINER**